PPQ Stakeholder Meeting
December 10, 2003
Breakout Session Summary

Pest Risk Assessments (PRA's) Panel Discussion

Panel Members:
1. Bob Griffin, *APHIS, PPQ, Center for Plant Health Science and Technology (CPHST), Director of the Pest Epidemiology and Risk Analysis Lab*
2. Dorothea Zadig, *California Department of Food and Agriculture, Program Supervisor for Strategic Planning and Pest Risk Analysis*
3. Scott Fister, *Vermont Department of Food and Agriculture, State Plant Regulatory Official and Secretary/Treasurer of the National Plant Board (NPB)*
4. Lin Schmale, *Society of American Florists, Senior Director of Government Relations*
5. Faith Campbell, *American Lands Alliance, Environmental Advocate focusing on Invasive Species, Weeds, Forest Pests and Diseases*
6. Erich Rudyj, APHIS/PPQ, Facilitator and Dore Mobley, APHIS/LPA, Recorder

I. Purpose: To review PPQ's PRA models, process, and stakeholder participation and to make recommendations for improvement.

II. Synopsis of Panelist's Presentations:

1) Bob Griffin, *APHIS, PPQ, Center for Plant Health Science and Technology (CPHST), Director of the Pest Epidemiology and Risk Analysis Lab*

The SPS agreement was signed in 1995 along with the formation of the WTO, marking the point where governments that signed the WTO would have to perform risk assessments. Under the SPS agreement countries will base their decisions either on international standards or risk assessments. There are now 19 international standards in place but most decisions are still based on risk assessments. Risk analysis is evolving. A lot of countries are still coming on board and the US provides a great deal of leadership. Risk analysis is being institutionalized within PPQ; it is becoming ISO certified and is working to comply with international standards. PPQ's PRA's are generally performed by CPHST, some by contractors and export countries. PRA guidelines were developed primarily for commodities; and new versions are forthcoming. PRA's are performed for fruits, vegetables, regulated articles, conveyances, and programs. There are organism assessments performed for new pests, invasive species, biological control agents, and export products. CPHST has approximately 30 specialists performing PRA's. In FY 2003 they preformed forty (40) commodity PRA's and eighteen (18) other types.

2) Dorothea Zadig, *California Department of Food and Agriculture, Program Supervisor for Strategic Planning and Pest Risk Analysis*

The SPS agreement covers risk assessment, the IPPC talks about risk analysis. The terms are used synonymously. When working with APHIS there is a process for risk management and risk analysis, and together the two become the risk assessment process. The Safeguarding Review discussed "stakeholders". When stakeholders become estranged from APHIS, the regulatory process becomes political and there is a delay in getting Rules passed. The Safeguarding Review looked for new opportunities to involve stakeholders and limit the amount of "paralysis". Stakeholders are concerned about being heard and having regulatory capture. There is opportunity for involvement/participation. Discussion is needed on how to involve stakeholders in the risk process and in leveraging their expertise.

3) Scott Pfister, ***Vermont Department of Food and Agriculture, State Plant Regulatory Official and Secretary/Treasurer of the National Plant Board (NPB)***

PRA's are used for import/export analysis; this is the most contentious use. Other areas were they are important is pest detection and quarantines. PRA's must be science driven. States may use the APHIS PRA to expedite and prioritize their own work. The NPB believes that there is a definite need for good assessments. States agree that transparency is a big issue. Transparency is needed during the preliminary process. At the time the PRA is published for public comment it is well into the process for the comments to have a real impact. A lack of information has led to an assumption of low risk. The converse is actually true. "When in doubt keep it out" becomes the default position. States have the expertise and desire to be involved. There is a need to compile historical information and references, and store it in a web based system for easy access. There needs to be follow up to ensure that the assumptions made during the analysis are correct. States should be invited to visit foreign countries when preparing a risk assessment. When countries don't allow US imports for non scientific reasons, the US should do the same. Fairness is the issue.

4) Lin Schmale, ***Society of American Florists, Senior Director of Government Relations***

The Society of American Florists represents horticultural growers. The panel needs to think about the whole risk analysis process not just the assessment. What are we going to do about improving the process. Geraniums and *Ralstonia* are a good example of the value of stakeholder involvement in the risk analysis and risk management process. The industry had a lot of knowledge and experience so it made sense for them to advise APHIS about industry practice before APHIS spent a lot of time going down the wrong path. Industry needs to be involved in a meaningful way to increase the knowledge on which APHIS can base its scientific and management decisions. Lessons learned from *Ralstonia* include a need for better tracking of individual shipments and developing better industry practices. Industry looks forward to continuing the relationship with APHIS

5) Faith Campbell, ***American Lands Alliance, Environmental Advocate focusing on Invasive Species, Weeds, Forest Pests and Diseases***

There is a need for transparency and a need to expand the concept of stakeholders. Environmentalists need to be valued and can help make the case for policy and regulatory controls. Risk assessments are getting better but they do not allow enough recognition of uncertainties. The process was developed by people that had fewer unknowns so assumptions need to be checked. There is a need to ensure that mitigation measures are representative. If an organism has not been evaluated it is not a quarantine pest; however, when it is subsequently found there is scramble to make a determination if it is actionable. Is it still an issue that APHIS does not have authority to act on pests that entered the country but have not yet been evaluated as to their quarantine status? In regards to the risk management process; decisions are made in a very secretive way and in some cases may be contrary to the risk analysis. There is never an explanation as to how decisions were made. Follow up to ensure that assumptions are met, follow up on the mitigation measures, and the evaluation process needs to be defined and raised in priority. Early stakeholder involvement should be improved.

III. Group Discussion Points:

Greater Stakeholder Involvement and Support

- Expand the definition of stakeholders to include environmentalists, academia, etc. – become broader.
- Stakeholders, including industry feel shut out of the PRA process. Stakeholder involvement (more than just "reviews") is critical since agriculture is affected after the pest is already here.

- The full range of stakeholders should be included in the full range of PRA, risk management, and work plan issues.
- APHIS can anticipate support from industry as its "shareholders" in the PRA process.

Pest Risk Assessments

- PRA's are getting better, in general they are sound, but improvements are needed; such as dealing with "uncertainty". Unknown does not equal no risk. EPA does an uncertainty analysis, this might be worth emulating.
- Data quality is a big issue. Sudden oak death (SOD) on rhododendrons is a testament that the regulatory process did not work very well. During the five years that APHIS was working on the rulemaking, the fact that the Dutch had this problem never surfaced.
- APHIS must be more honest, recognizing that the foreign countries may not be forthright.
- We need to look at the abilities of the certifying foreign country when determining risk.
- Understandable risk assessments are needed; ORASIBA (Clementines) was one.
- By publicly having to explain PRA thinking, agencies are sure of their results. Future PRA's need clearer oral and written explanations on data quality, uses of models, and R&D methods.
- PRA growth areas include:
    - Q-37 revision
    - Noxious weeds
    - Wetlands and Rangelands impacts
    - Invasive species issues

Level of Acceptable Risk

- PRA's are meaningless if we are not clear about what is an acceptable level of risk. On a case-by-case basis, APHIS needs to determine what is acceptable.
- This is the most important policy decision that needs making and it needs to be made publicly.
- Everyone may have a different level of risk so consensus building is needed. APHIS needs to set the goals and then develop the assessment and management plans based on those goals.
- The acid test is to have an affected industry help define the level of risk that is acceptable. Industry shares part of the burden.
- A defined level of risk is important as long as we understand that there is no such thing as zero risk. Zero risk means zero trade. More discussions are needed.
- A workshop convened to address this issue may prove useful.

Peer (Independent) Review

- Some stakeholders favor independent reviews; there is this perception that only a narrow, internal circle is called upon to comment on a PRA. A broad range of stakeholders is desired.
- Some industries desire peer review because it is perceived as a stepping stone to transparency. Other agencies are using it; e.g. the EPA process.
- If the PRA is controversial or politically driven then peer review is a great tool. It would also help leverage technical expertise.
- The PRA public comment period is too late in the process to be considered a "peer review"; peer review is an independent, technical panel.
- Peer reviews should not be the "academic type". Issues should include data quality, data interpretation, model selection, and a plug-in to risk management.
- Peer review is good as long as it remains balanced. Competition can unfairly bias the analysis.
- Peer review usefulness needs further discussion. APHIS has not often gotten valuable comments from peer reviewers because they are not familiar with the foreign pests.
- APHIS' PRA could benefit from the creation of a science advisory board to focus on this issue.

External Technical Expertise

- APHIS should make greater use of State panels and technical panels. It should leverage existing technical knowledge and expertise; for capacity, quality, and timeliness.

Risk Mitigation/Management

- Once the assessment is developed, it makes sense to have the industry and others involved in the risk mitigation phase. The end product will be more reflective of the risks.
- Risk assessment and risk management should not be separated.
- The basis of risk management are unclear; appearing secretive. Risk management and risk analysis plans may not align; a decision in one does not often conform to an action in the other.
- Off-shore pest tracking and mitigations are important.
- Process monitoring and follow-up is important to ensure complete and accurate assumptions.
- Alternative or equivalent mitigations should be explored and considered.

Work plans

- Work plans are sensitive and risk management plans include a work plan synopsis but the industry would welcome an opportunity to comment on work plan effectiveness.

Transparency

- APHIS should expand and implement better process transparency. Transparency can be better achieved through use of States, industry, environmentalist, and university partners.
- The underlying documentation is just as important as the assessment itself. APHIS needs to make that information available without the industry having to ask for it.
- Transparency is good but must be "balanced" because of fair/unfair competition questions.

Emergencies, Quarantine and Non-Quarantine Pests, Data Collection and the DHS Issue

- How do you quantify rates for quarantine pests (modeling)? This is a growing area. There is much concern about the quality of data collection since those functions were transferred to DHS. There is an initiative underway to address this issue!
- Organisms that are not quarantine pests still need to be addressed. It is risky to allow things into the country because it is not listed at time of entry quarantine pest.
- The evaluation of emergency program pests is missing. When a new pest comes along a decision is made based on the available information.
- Data/Document archives, readily accessible and well organized, would be useful in making rapid decisions.

IV. Summary Presentation to Plenary Session

Generally PRA's are sound; comments involve communication, transparency, and involvement

- Greater Stakeholder Involvement
  - Broaden Definition of Stakeholders
  - Early and Full Involvement in Risk Management and Work Plans
  - Early and Full Involvement in Risk Assessment Process
- Independent/Peer Review Process
  - Science Policy and Interpretation
- Leverage Technical Expertise and Resources
  - Capacity
  - Quality

    - Timeliness
    - Verification and Compliance
- Discussion and Definition of “Levels of Appropriate Risks”

V. Session Stats

✓ 5 panelists and 27 audience participants